

NDA 19-813/S-026

Aiza Corporation
1900 Charleston Road
P.O. Box 7210

NOV 1 2000

Mountain View, CA 94039-72 10

Attention: Janne Wissel
Sr. Vice President, Operations

Dear Ms. Wissel:

Please refer to your supplemental new drug application dated January 26, 2000, received January 27, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duragesic (fentanyl transdermal system).

This "Changes Being Effected" supplemental new drug application provides for changes to the 25, 50, 75, and 100 ug/h pouchstock.

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MED WATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sara Shepherd, Project Manager, at (301) 827-7430. Sincerely.

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Inactive Ingredients: Hydroxyethyl cellulose, ethylene vinyl-acetate copolymer, silicone adhesive between polyester backings.

Dosage: For information for use, see accompanying product literature.

Apply immediately upon removal from pouch.
Do not store unpouched or above 77°F (25°C).

DO NOT USE IF SEAL ON POUCH IS BROKEN

KEEP OUT OF REACH OF CHILDREN

See patient instructions for disposal information.

Manufactured by:
ALZA Corporation
Mountain View, CA 94043

Distributed by:
JANSSEN PHARMACEUTICA INC.
Titusville, NJ 08560

DURAGESIC® 25µg/h 
(FENTANYL TRANSDERMAL SYSTEM)

NDC 50458-033-05

Five (25µg/h) Systems

DURAGESIC® 25µg/h 
(FENTANYL TRANSDERMAL SYSTEM)

In vivo delivery of 25µg/h fentanyl for 72 hours

NOT FOR ACUTE OR POSTOPERATIVE USE

Each transdermal system contains:
2.5 mg fentanyl and 0.1ml alcohol USP

DO NOT USE IF SEAL ON POUCH IS BROKEN

KEEP OUT OF REACH OF CHILDREN

Rx only



JANSSEN
PHARMACEUTICA

Inactive Ingredients: Hydroxyethyl cellulose, ethylene vinyl-acetate copolymer, silicone adhesive between polyester backings.

Dosage: For information for use, see accompanying product literature.

Apply immediately upon removal from pouch.

Do not store unpouched or above 77°F (25°C).

For your convenience in recording narcotic use,

INITIAL/DATE

1. _____ 2. _____ 3. _____

4. _____ 5. _____

NSN#6505-01-335-9391

For questions concerning this product please call the Janssen One to One™ Customer Action Center at 1-800-JANSSEN (1-800-526-7736) 8 A.M. to 8 P.M. EST, Monday through Friday.

Manufactured by:
ALZA Corporation
Mountain View, CA 94043

Distributed by:
JANSSEN PHARMACEUTICA INC.
Titusville, NJ 08560

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PHARMACEUTICA

DURAGESIC® 75µg/h 
(FENTANYL TRANSDERMAL SYSTEM)

NDC 50458-035-05

Five (75µg/h) Systems

DURAGESIC® 75µg/h 
(FENTANYL TRANSDERMAL SYSTEM)

In vivo delivery of 75µg/h fentanyl for 72 hours

NOT FOR ACUTE OR POSTOPERATIVE USE

Each transdermal system contains:
7.5mg fentanyl and 0.3ml alcohol USP

DO NOT USE IF SEAL ON POUCH IS BROKEN

KEEP OUT OF REACH OF CHILDREN

Rx only



JANSSEN
PHARMACEUTICA

**FOR USE IN
OPIOID TOLERANT
PATIENTS**

DURAGESIC® 100µg/h 
(FENTANYL TRANSDERMAL SYSTEM)

NDC 50458-036-05

Five (100µg/h) Systems

DURAGESIC® 100µg/h 
(FENTANYL TRANSDERMAL SYSTEM)

In vivo delivery of 100µg/h fentanyl for 72 hours

NOT FOR ACUTE OR POSTOPERATIVE USE

Each transdermal system contains:

10mg fentanyl and 0.4ml alcohol USP

DO NOT USE IF SEAL ON POUCH IS BROKEN

KEEP OUT OF REACH OF CHILDREN

Rx only

**FOR USE IN
OPIOID TOLERANT
PATIENTS**



JANSSEN
PHARMACEUTICA